Options for managing low grade cervical abnormalities detected at screening: cost effectiveness study

_Trial of Management of Borderline and Other Low grade Abnormal smears (TOMBOLA) Group_

**Record Status**

This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

**CRD summary**

The objective was to determine the cost-effectiveness of three management strategies for low-grade cervical abnormalities detected at screening. The authors concluded that none of the three strategies could be defined as more cost-effective than the other two. The methods were sound and the results were presented clearly. The authors’ conclusions appear to be appropriate.

**Type of economic evaluation**

Cost-utility analysis

**Study objective**

The objective was to determine the cost-effectiveness of three management strategies for low-grade cervical abnormalities detected at screening.

**Interventions**

The strategies were cytological surveillance, referral to colposcopy for biopsy and recall if necessary, and referral to colposcopy with immediate treatment based on the colposcopic appearance.

**Location/setting**

UK/secondary care.

**Methods**

**Analytical approach:**

This economic evaluation was based on data from a single study with a three-year time horizon. The authors stated that the analysis was carried out from the perspectives of the UK National Health Service (NHS) and society.

**Effectiveness data:**

The clinical data came from a randomised controlled trial (RCT) with 4,201 women with low grade abnormalities. There were 2,219 women in the cytological surveillance group, 1,000 in the colposcopy with biopsy and recall group, and 982 in the colposcopy with immediate treatment group. The length of follow-up was 36 months. The details of the RCT were reported elsewhere (Cotton, et al. 2006, see ‘Other Publications of Related Interest’ below for bibliographic details). The key clinical endpoint was the number of cases of cervical intra-epithelial neoplasia detected.

**Monetary benefit and utility valuations:**

The utility values were based on the European Quality of life (EQ-5D) questionnaire scores for women in the RCT. The EQ-5D was completed before initial randomisation and at 12, 18, 24, and 30 months.

**Measure of benefit:**

The primary measure of benefit was quality-adjusted life-years (QALYs), which were estimated using the decision model. The QALYs were discounted at an annual rate of 3.5%, for the NHS perspective, and were not discounted, for the societal perspective.

**Cost data:**

The analysis included the direct costs and those of productivity lost. The direct costs were for smear tests, colposcopy
examinations, treatment, hospital visits, and complications. The productivity costs included time taken for consultation and treatment, and expenses for travel to appointments for women and their companions. The resource use data were from questionnaires completed by the trial participants. The unit costs were from national sources and published studies, using itemised costs for the UK. Published average wages were used for the productivity costs. The price year was 2004 and costs were converted to 2004, using the hospital and community health services pay and price index. All costs were presented in UK pounds sterling (£) and they were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
Monte Carlo simulation was performed to investigate the impact of parameter uncertainty on the cost-effectiveness ratios.

Results
The strategy of colposcopy plus biopsy and recall was associated with the highest mean discounted QALYs at 2.181, followed by colposcopy plus immediate treatment at 2.149, and cytological surveillance at 2.129.

The mean discounted costs to the NHS were £241.1 with colposcopy plus biopsy and recall, £240.3 with colposcopy plus immediate treatment, and £150.2 with cytological surveillance. The costs to society were £327.5 with colposcopy plus biopsy and recall, £339.9 with colposcopy plus immediate treatment, and £204.4 with cytological surveillance.

From the NHS perspective, the incremental cost-effectiveness ratio (ICER) was £4,546 per QALY gained for immediate treatment versus surveillance and £26 per QALY gained for biopsy and recall versus immediate treatment. From the societal perspective, immediate treatment was dominated as it was more expensive and less effective than biopsy and recall. The cost per QALY gained for biopsy and recall versus surveillance was £2,373.

The results of the Monte Carlo simulation indicated that the 95% confidence intervals for the ICERs were very wide. For example, for the societal ICER of £2,373, the 95% confidence interval was -£24,651 to £25,770.

Authors' conclusions
The authors concluded that none of the three strategies could be defined as more cost-effective than the other two.

CRD commentary
Interventions:
The strategies appear to have been appropriate as they were the relevant options for the management of low-grade cervical abnormalities.

Effectiveness/benefits:
The clinical analysis was based on a RCT with a large sample, which was potentially a good source of evidence. The authors provided no details for the RCT, which was reported elsewhere. The approach used to derive the benefit measure was clear and appropriate. QALYs are a comprehensive measure of benefit.

Costs:
The categories of costs were consistent with the perspectives. The unit costs and resource quantities were presented. The sources of the costs were reported, as were other details, such as the currency, discounting, and the price year. This enhances the ability to replicate the analysis in other settings and time periods.

Analysis and results:
A full incremental cost-effectiveness analysis was not performed. The issue of uncertainty was addressed, using Monte Carlo simulation. The authors presented the study results in detail and they reported its limitations, particularly that long-term costs due to cancer were not considered.

Concluding remarks:
The methods were sound and the results were presented clearly. The authors' conclusions appear to be appropriate.
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